LONDAX® HERBICIDE

(bensulfuron methyl)

DIETARY EXPOSURE ASSESSMENT

HEALTH ASSESSMENT SECTION

MEDICAL TOXICOLOGY BRANCH

DEPARTMENT OF PESTICIDE REGULATION

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

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EXECUTIVE SUMMARY

RISK ASSESSMENT

The risk assessment process incorporates four basic components. These include; hazard identification, dose-response evaluation, exposure assessment, and risk characterization.

Hazard identification involves assembling data and evaluating the toxicological effects of a given chemical. Hazard identification seeks to establish the likelihood that the toxic properties of a chemical can be assumed from one situation to another, e.g., extrapolating from animal models to potential effects in humans.

Dose-response evaluation involves describing the quantitative relationship between chemical exposure and the associated toxic response. The basic premise of toxicology is that at a high enough dose, virtually all substances will cause toxic manifestations. Chemicals are often referred to as "dangerous" or "safe", as though these concepts were absolutes. In reality, however, these terms describe the dosage required to cause toxic effects (i.e., if a low dosage is needed, the chemical is considered dangerous). A chemical's toxic potential is generally determined by a battery of experiential studies. These studies examine both the toxic effects of a chemical and the exposure levels (doses) at which an effect is seen. State and federal testing guidelines stipulate that substances are to be tested at doses up to the "limits of toxicity" (i.e., doses which provide evidence of a toxic effect in the experimental system). These dose levels can, however, be many times higher than potential human exposure. This must be addressed in the exposure assessment and risk characterization components of the risk assessment process.

Exposure assessment involves describing the population exposed to a particular agent, and the nature of the exposure. The exposure can be previous, existing, or anticipated.

Risk characterization usually involves the integration of the major components of the risk assessment process. This generally results in a summary of the results and conclusions from the first 3 components. It addresses the likelihood of humans experiencing the toxicological effects of the agent in question. In the absence of exposure data, hypothetical risk may be inferred by the use of the hazard identification and dose-response components only.

DIETARY RISK ASSESSMENT FOR LONDAX®

Under the provisions of Assembly Bill 2161 (Bronzan), analysis of potential dietary exposure, to Londax® Herbicide (active ingredient bensulfuron methyl), has been conducted by the California Environmental Protection Agency, Department of Pesticide Regulation (DPR).

Londax® is a product of E.I. du Pont de Nemours and is used to control many broad leaf and sedge weeds in rice crops. The herbicide is registered only for use on rice, as most other crops would be sensitive to its herbicidal effects.

For Londax\, the toxicology studies were evaluated. Potential adverse effects were noted and NOEL's (no observed effect levels) were selected for assessment of both acute and chronic dietary exposure.

For acute exposure, an adequate single-dose study was not available. A rat teratology study was, therefore, used for evaluating acute dietary exposure (Haskell, 1984). The NOEL used was 35 mg/kg (body weight) and was based on retarded and abnormal developmental variations in fetuses. In using this NOEL, it was assumed that developmental effects seen after multiple doses would be expressed following a single exposure. Furthermore, since teratogenic end-points are only relevant for women of child-bearing age, it was assumed that all other population sub-groups were as sensitive as this group. Both of these assumptions may underestimate the actual NOEL for single-dose exposure.

For chronic exposure, a NOEL of 19.9 mg/kg/day was obtained from a 1 year feeding study with dogs (Bio/dynamics, 1986). This NOEL was based on minor liver effects seen at the next highest dose (230 mg/kg/day).

Exposure assessment generally utilizes chemical residue values and consumption estimates. In the absence of residue information, tolerances (permissible levels of the pesticide in commodities) are generally used to estimate residue values. Fish and rice (commodities associated with label approved use of Londax\) are not currently monitored for Londax® residues. Furthermore, field studies have indicated that Londax® residue values are less than detection levels. Tolerances, therefore, were used in this dietary assessment as a hypothetical "extreme case" scenario. The tolerances used were established by the U.S. Environmental Protection Agency in 1989. Consumption estimates were based on data from a nationwide food consumption survey, conducted by the U.S. Department of Agriculture in 1987 and 1988.

Using the estimated dietary intake and experimentally determined NOEL's, margins of safety (MOS's) were estimated for the U.S. population and various population subgroups. MOS's were estimated by dividing NOEL's by the estimated dietary intake. For the U.S. population and all population subgroups examined, the MOS's were 2×10^5 or greater.

Based on the current analysis, the Department of Pesticide Regulation concludes that the margins of safety, for dietary exposure to Londax®, (active ingredient bensulfuron methyl) are adequate to protect human health.

I. INTRODUCTION

Section 13060 of the Food and Agricultural Code of California established the requirement for CDFA (the California Department of Food and Agriculture), in conjunction with CDHS (the California Department of Health Services), to conduct a risk assessment on the dietary exposure to pesticides in both raw and processed foods. As of July 17, 1991, this responsibility was transferred to the Department of Pesticide Regulation, California Environmental Protection Agency. This document addresses the potential dietary exposure to Londax® (active ingredient - bensulfuron methyl) residues on raw agricultural commodities.

Londax® Herbicide is a dry flowable formulation selective for pre-emergence and early post-emergence weed control in water seeded rice. Londax® contains 60% bensulfuron methyl, Methyl 2[[[[[(4,6-dimethoxypyrimidin-2-yl)amino]carbonyl]amino]sulfonyl] methyl] benzoate.

In the state of California, Londax® can be applied either as solution (in water) or by air (without a liquid carrier). The herbicide should be applied at a rate of 1 2/3 ounces of product (equivalent to 1 oz active ingredient) per acre. The application should be post flooding, directly into standing water of the rice field. The water level at the time of application, and within 5 days of application, should be high enough for the field to be completely covered (preferably at least 3 inches with no exposed soil).

Londax® rapidly inhibits growth of susceptible weeds. Leaves of susceptible plants will appear chlorotic in 3 to 5 days following application. Necrosis of the growing point will subsequently occur. Susceptible plants will be controlled in 7 to 21 days. Effectiveness of the herbicide may be delayed if air or water temperatures drop below 65 degrees Fahrenheit.

Londax® is manufactured by E.I. du Pont de Nemours and was the first formulation submitted for Section 3 registration with bensulfuron methyl as the active ingredient.

II. TOXICOLOGY PROFILE

A. ACUTE TOXICITY

The acute toxicity profiles, for both the technical grade material and a sample containing 60% active ingredient (ai), has been generated (Haskell, 1981a-b, 1982, 1983a, 1984a-i, 1986a-f; Hazleton 1983, 1984). The results are summarized in Table I.

TABLE I: Acute toxicity of Londax® Technical and Londax® formulation (60% active ingredient).

Londax® Technical	
Oral LD_{50} (rat)	>5,000 mg/kg
Dermal LD_{50} (rabbit)	>2,000 mg/kg
Inhalation LC_{50} (rat, 4-hour)	>5.0 mg/L
Eye Irritation (rabbit)	Negative
Dermal Irritation (rabbit)	Negative
Dermal Sensitization	Negative
Londax® Formulation (60% ai)	
Oral LD_{50} (rat)	>5,000 mg/kg
Dermal LD_{50} (rabbit)	>2,000 mg/kg
Inhalation LC_{50} (rat, 4-hour)	Not Required
Eye Irritation (rabbit)	Slight to Mild
Dermal Irritation (rabbit)	Negative
Dermal Sensitization	Negative

B. SUB-CHRONIC TOXICITY

1. Dietary Study (Mouse)

Mice were fed Londax® (95% ai) for 13 weeks at levels of 0, 300, 1,000, 3,000, or 1,0000 ppm *(approximately 40, 130, 400, or 1,400 mg/kg/day)* (Institute of Environmental Toxicology, 1984). Minor effects observed included increased liver weight, cloudy liver color and centrilobular swelling. The "no observed effect level" (NOEL) was 300 ppm (40 mg/kg/day) based on an increase in liver/brain weight ratios in males.

2. Dietary Study (Rat)

Rats were fed Londax® (96-99% ai) for 90 days at levels of 0, 100, 1,500, or 7,500 ppm *(approximately 6, 100, or 500 mg/kg/day)* (Haskell, 1983b). Minor effects included increased relative liver weights, decreased staining of the centrilobular region, elevated body and organ weights, and mild hemolytic anemia. There were no dose-related clinical signs. The NOEL was 1,500 ppm (100 mg/kg/day) based on toxicological effects at the next highest dose (7,500 ppm).

3. Dietary Study (Dog)

Dogs (Beagles) were fed Londax® (95% ai) for 90 days at levels of 0, 100, 1,000, or 10,000 ppm *(approximately 3, 30, or 320 mg/kg/day)* (Haskell, 1985a). Effects were noted only at the high dose. These included; increased serum alkaline phosphatase and alanine aminotransferase, increased liver weights, bile stasis, centrilobular hepatocellular swelling, hepatocyte necrosis and calculi in the gall bladder. The NOEL was 1,000 ppm (30 mg/kg/day) based on the liver effects at 10,000 ppm.

C. METABOLISM (Rat)

Metabolism of ^{14}C-labeled Londax® was studied in male and female rats (Haskell, 1984j). This study had a number of inconsistencies with state and federal guidelines and was, therefore, considered unacceptable and not upgradeable. An agreement was made to repeat the study.

The repeat metabolism study was performed in conjunction with an absorption, distribution, and excretion study in Sprague Dawley rats (Hazleton, 1990). Radio-labeled Londax® was administered, by gavage, at doses of 20 or 1,000 mg/kg. An additional group of animals was treated with 20 mg/kg labeled Londax® following 15 days pre-treatment with cold (non-labeled) material. Maximum plasma levels of radio-isotopes were obtained, typically, within 1 to 6 hours of dosing. Secondary peaks generally occurred 12 hours after dosing. Plasma levels were not detectable by 72 hours post-dosing. The mean elimination half-life ranged from 5 to 9 hours. No sex differences in pharmacokinetics or metabolism were detected. No evidence of tissue bioaccumulation was detected. Major metabolites included demethylated bensulfuron methyl, sulfonylurethan and an unidentified polar metabolite. The study did have a number of deficiencies and was, therefore, considered unacceptable. The deficiencies included: 1) the lack documentation concerning the actual concentrations of active ingredient in dosing solutions; and 2) the lack of documentation reporting the frequency of sample preparation of the non-labelled test article. Acceptability of this study by DPR is contingent on the submission of acceptable data and documentation to address the deficiencies.

D. CHRONIC TOXICITY

1. Dietary Study (Rat)

Sprague Dawley rats were exposed to Londax®, in their diet, for 24 months at levels of 0, 50, 750 or 7,500 ppm *(approximately 4, 60, or 600 mg/kg/day)* (Haskell 1985b). After 12 months, 10 rats from each sex and dose group were killed and necropsied. No dose-related gross abnormalities were seen at either the 12 or 24 month necropsies. Minor histological changes were observed in livers at 7,500 ppm (both 12 and 24 month). There were, however, no dose-related proliferative lesions. Decreases in food consumption and body weight gain occurred in females from the high dose group. In the high dose males (24 months) mild anemia was detected. The NOEL was 750 ppm (60 mg/kg/day), based on the toxicological effects reported at 7,500.

2. Dietary Study (Dog)

Dogs (Beagles) were exposed to Londax®, in their feed, at concentrations of 0, 50, 750, or 7,500 ppm *(approximately 1.4, 19.9, or 230 mg/kg/day)* for 1 year (Bio/dynamics, 1986). No dose-related clinical signs were observed. Minor liver effects (e.g., increased alanine aminotransferase, alkaline phosphatase, and liver weights) and brown material in bile canaliculi were detected at 7,500 ppm. The NOEL was, therefore, assigned the value of 750 ppm (19.9 mg/kg/day).

E. ONCOGENICITY

1. Dietary Study (Mouse)

Mice were fed 0, 10, 150, 2,500, or 5,000 ppm *(approximately 0.9, 13.5, 226, or 457 mg/kg/day)* Londax® for 104 weeks (Institute of Environmental Toxicology, 1986). No dose-related mortalities nor dose-related clinical signs were detected. Centrilobular swelling (males), cortical cysts and pelvic dilation in kidneys (females) and focal hepatocellular necrosis (females) occurred at 5,000 ppm. These effects were considered an indication that a maximum tolerated dose had been achieved. The NOEL for these effects was 2,500 ppm (226 mg/kg/day).

2. Dietary Study (Rat)

See Chronic Toxicity in Rat.

F. REPRODUCTION

1. Dietary Study (Rat)

Twenty rats/sex/dose were used from the chronic study (above) as a two generation, four litter reproduction study. First generation animals (F_0)

were initially mated on days 97-112 (Haskell, 1985b). These animals were necropsied after a 1 or 2 year exposure to Londax\. No dose-related mortality or abnormal clinical chemistry was observed in the F_0 generation animals. Furthermore, no dose-related gross pathology was observed at 1 or 2 years. Minor histological changes were noted in the livers of animals from the 7,500 ppm group. Decreased food consumption and body weight gain occurred in F_0 females from the 7,500 ppm group. No dose-related effects on fertility, fecundity or offspring viability was detected. No dose-related pathology was observed in F_{2b} animals. The NOEL for reproductive effects was the highest dose tested, i.e., 7,500 ppm (approximately 600 mg/kg/day).

G. TERATOLOGY

1. Gavage Study (Rat)

Londax® (approximately 95% ai) was administered, by gavage, to female rats on days 7 through 16 of gestation (Haskell, 1984k). Nominal dose levels included 0, 50, 500 and 2,000 mg/kg body weight. The material was not maternally toxic at administered dose levels; however, a dose-related increase in variations (retarded and abnormal development) was detected among fetuses in the 500 and 2,000 mg/kg groups (see Section III for more details). The NOEL for maternal toxicity was 2,000 mg/kg (the highest dose tested). The NOEL for the conceptus was 50 mg/kg, based on effects observed at 500 and 2,000 mg/kg. Chemical analysis of the active ingredient indicated that the actual dosages ranged from 44 to 94% of the nominal doses. The NOEL's after adjusting for analytical recoveries were 1374 mg/kg for maternal effects and 35 mg/kg for the fetal response.

2. Gavage Study (Rabbit)

Artificially inseminated rabbits were dosed with Londax\, in 0.5% methyl cellulose, on gestation days 7-19 (Haskell, 1985c). Dosing was by gavage at 0, 30, 300, or 1,500 mg/kg/day. Maternal toxicity observed at the high dose included decreased body weight, decreased food consumption, abortion (1/20), complete fetal resorption (2/20), and death (2/20). Based on these data, the maternal NOEL was 300 mg/kg. No dose-related fetotoxicity or fetal malformations were detected. A decrease in fetal weight gain was observed at 1,500 mg/kg. An association between fetal weight gain and maternal toxicity was concluded.

H. GENOTOXICITY

1. Gene Mutation

a. Bacteria

Londax® (95% ai) was tested in the *Salmonella* gene mutation assay (Ames test), in tester strains TA98, TA100, TA1535 and TA1537, in the presence and absence of exogenous metabolic activation (Haskell, 1981c). No induced revertants were detected when the test article was tested at concentrations ranging from 0.01 to 25 ug/plate, (i.e., Londax® was not considered mutagenic in this bacterial system).

b. Mammalian cells

Londax® (95.9% ai) was tested for mutagenic potential in the CHO (Chinese hamster ovary) /HGPRT (hypoxanthineguanine phosphoribosyl transferase) gene mutation assay (Haskell, 1984l). No dose-related increase in mutants (expressed as resistance to 6-thioguanine), at Londax® concentrations of 0.5 to 4.0 mM, were detected.

2. Structural Chromosomal Aberration

In Vivo cytogenetics

Londax® was tested for the potential to induce chromosomal aberrations in bone marrow cells of rats (Haskell, 1984m). The test article was administered by gavage. Rats were subsequently killed 6, 22, or 48 hours later. Bone marrow cells were then isolated, processed and scored for chromosomal aberrations. Doses used for this study were 0, 500, 1,500, 5,000 mg/kg. No toxic effects were detected. No dose-related induction of chromosomal aberrations was detected.

3. Other Genotoxic Effects

a. *In Vitro* Unscheduled DNA Synthesis

Londax® (95.5% ai) was tested, *in vitro*, for DNA damage and repair potential in the primary hepatocyte UDS (unscheduled DNA synthesis) assay (Haskell, 1984n). No dose-related effects were observed when tested up to 3.5 mM.

b. *In Vitro* Sister Chromatid Exchange

Londax® (95.9% ai) was tested for the potential to induce sister chromatid exchanges in cultured CHO cells (Haskell, 1986g). Test concentrations ranged from 0 to 2.7 mM. An apparent increase in sister chromatid exchanges (1.4 x background) was reported for the top two doses (1.35 and 2.7 mM) in the absence of metabolic activation.

III. HAZARD IDENTIFICATION/DOSE-RESPONSE EVALUATION

A potential adverse effect (i.e., increase in overall fetal abnormalities) was detected when Londax® was tested in a rat teratology study (Haskell, 1984k).

For the study in question, Sprague Dawley rats were treated, by gavage, with Londax® (approximately 95% ai) on days 7 through 16 of gestation. Nominal dose levels were 0, 50, 500 and 2,000 mg/kg body weight.

The test material was not maternally toxic at administered dose levels. Furthermore, no adverse effects were detected, with respect to the incidence of pregnancy, corpora lutea, implantation sites, resorptions, or live fetuses. The mean body weight of fetuses in the 50 and 2,000 mg/kg groups were significantly lower than the control value ($p<0.05$). The biological significance of this, however, is questionable due to the small differences and lack of a dose-response relationship.

The average percent of fetuses (per litter) with developmental variations (abnormalities) is presented in Table II. For total variations, a dose-related increase in abnormalities was detected. The percent of abnormal fetuses, at 500 and 2,000 mg/kg, was significantly greater ($p<0.05$) than observed in control animals (0 dose point). A dose-related increase was also detected for fetal variations classified as "retarded development" (e.g., partially ossified or unossified bone). For "abnormal development" (e.g., extra ossification center of the lumbar region of the ribs), each dose group exhibited elevated levels of variations, when compared to background (controls), with a statistically significant ($p<0.05$) increase at 2,000 mg/kg.

Table II: Fetal variations per litter as a function of Londax® dose. The mean percent of fetuses with abnormalities are presented as total variations, those due to retarded development, and those due to abnormal development.

	DOSE (mg/kg/day)			
EFFECT	0	50	500	2,000
Total Variations	51 (4.7)	61 (4.7)	65 (5)*	64 (4.8)*
Retarded Development	43 (5.8)	52 (5.9)	55 (5.7)	55 (5.5)
Abnormal Development	20 (2.6)	26 (4.7)	22 (3.1)	26 (3.0)*

* indicates that the registrant reported a statistically significant ($p<0.05$) increase over background (controls).

() standard deviation.

Fetal variations contributing to the overall increase included incompletely ossified sternebrae, extra ossification centers of the lumbar region, and partially ossified or unossified hyoid bones. Table III presents these variations as a function of the percent of affected fetuses (as reported by the registrant). A dose-related increase in abnormalities is apparent for all three variation types with statistically significant increases detected at 2,000 mg/kg. Variations in the hyoid bones were statistically significant at 500 mg/kg as well.

Table III: Percentage of fetuses with abnormalities following exposure to Londax\. Abnormalities are broken down by specific variation.

	DOSE (mg/kg/day)			
EFFECT	0	50	500	2,000
Partial or no Ossification of Sternebrae	29	44	46	47*
Partial or no Ossification of Hyoid	9.3	18	24*	20*
Extra Ossification of lumbar region	2	5	10	16*

* indicates that the registrant reported a statistically significant ($p<0.05$) increase over background (controls).

While the above dose-related increases suggest agent associated effects, examining the variations as a function of the total number of fetuses may be misleading, i.e., a few aberrant litters could influence the overall findings. Data for incomplete ossification of the sternum were, therefore, converted to average variations per litter. For controls (background), the average number of fetuses with incomplete ossification in the sternum was 4.1% Table IV represents the number of litters exhibiting levels greater than background (i.e., greater than 4.1%).

Table IV: Litters with the number of abnormal fetuses greater than the average control value (4.1%).

	DOSE (mg/kg/day)			
EFFECT	0	50	500	2,000
Partial or no Ossification of Sternebrae	8 (24)	11 (20)	15 (23)*	17 (25)*

() the number of litters examined.

* indicates statistical significance ($p < 0.05$) with Fisher exact test.

As indicated, a dose-related increase in incomplete ossification of the sternebrae was observed. Using a Fisher exact comparison, both the 500 and 2,000 mg/kg groups exhibit a statistically significant increase ($p = 0.03$ for 500 mg/kg, and $p = 0.02$ for 2,000 mg/kg) when compared to control values. Based on the fetal effects observed at 500 and 2,000 mg/kg, the NOEL for this study was 50 mg/kg (35 mg/kg after adjusting for analytical).

Other organ-specific toxicities were reported in the sub-chronic and chronic studies (see Toxicology Profile section for details). The lowest NOEL observed in sub-chronic studies was ~30 mg/kg/day. This was primarily based on liver effects and altered serum enzyme concentrations. The lowest NOEL observed in chronic studies was 19.9 mg/kg/day. This was based on liver effects in a dog feeding study. The U.S. Environmental Protection Agency used this NOEL to set the Reference Dose (RfD) for Londax® at 0.2 mg/kg/day (20 / 100 (uncertainty factor)).

IV. EXPOSURE ASSESSMENT

Data on pesticide residues in food is necessary for conducting exposure assessments. These data are generally obtained from surveillance programs conducted by state and federal agencies. In the absence of residue information, tolerances (the highest permissible levels of the pesticide in commodities) are generally used as surrogate residue values. Fish and rice (commodities associated with label approved use of Londax\) are not currently monitored for Londax® residues. Furthermore, field studies have indicated that Londax® residue values are less than detection levels. Tolerances, therefore, were used in this dietary assessment as a hypothetical "extreme case" scenario. Tolerances for residues of Londax\, in or on specific raw agricultural commodities, have been established by the U.S. Environmental Protection Agency (EPA). For rice and rice straw, the EPA set tolerances at 0.02 and 0.05 ppm, respectively (Federal Register, 1989). For fish and potable water, EPA set a temporary tolerance of 0.3 and 0.1 ppm, respectively (Lindsay 1991).

Acute dietary exposure analyses were conducted using the Exposure-4™ computer program developed by TAS (Technical Assessment Systems, Inc., 1990). This software estimates the distribution of single-day exposures for the overall U.S. population and specific population subgroups. The analysis utilizes food consumption data, as reported in the 1987-88 USDA Food Consumption Survey. Exposure-4™ is designed to evaluate exposure to chemical residues as a function of user-days. A user-day is any day in which at least one commodity (containing the chemical residue) is consumed. Acute dietary intake for Londax® was based on the 95th percentile of user-day exposure.

Chronic dietary exposure analyses were conducted using the Exposure-1™ computer program developed by TAS (Technical Assessment Systems, Inc., 1985). This software also utilizes food consumption data, as reported in the 1987-88 USDA Food Consumption Survey. Exposure-1™ evaluates exposure based on daily consumption, of a given commodity, averaged over 365 days.

Table V shows the estimated exposure, in ug/kg (body weight)/day, for the major population sub-groups (see Appendix B for a more complete breakdown). The population sub-group exhibiting the largest estimated exposure was "Non-Hispanic-Other" (0.178 ug/kg/day for acute exposure and 0.016 ug/kg/day for chronic exposure).

TABLE V: Estimated dietary exposure to Londax® using tolerances. Dietary intake, in ug/kg/day, is estimated for acute and chronic exposure, for the indicated population sub-groups. Values are rounded to three decimal places.

Population Sub-group	Exposure (ug/kg body wt/day)	
	Acute[e,f]	Chronic[g]
U.S. Population	0.052	0.004
Hispanics	0.066	0.009
Non-Hispanic Whites	0.039	0.003
Non-Hispanic Blacks	0.056	0.007
Non-Hispanic Other	0.178	0.016
Nursing Infants (<1 year)	0.068	0.006
Non-Nursing Infants (<1 year)	0.081	0.023
Females (13+/P[a]/NN[b])	0.033	0.002
Females (13+N[c])	0.045	0.006
Children (1-6 years)	0.082	0.007
Children (7-12 years)	0.071	0.006
Males (13-19 years)	0.047	0.004
Females (13-19 years/NP[d]/NN)	0.040	0.003
Males (20+ years)	0.047	0.003
Females (20+/NP/NN)	0.045	0.003

[a] = pregnant
[b] = not nursing
[c] = nursing
[d] = not pregnant
[e] = Exposure is evaluated as a function of user-days (i.e., day which at least one commodity, containing Londax\, is consumed).
[f] = Values represent the 95th percentile of user-day exposure.
[g] = Exposure estimates are based on daily consumption, of a given commodity, averaged over 365 days.

V. RISK CHARACTERIZATION

Evaluation of potential acute dietary exposure is usually based on the lowest NOEL (no observed effect level) from single exposure animal studies. An adequate single-dose study for Londax® was not, however, available. The NOEL used for evaluating acute exposure was from a rat teratology study (Haskell, 1984/). The NOEL was 35 mg/kg (based on retarded and abnormal developmental variations in fetuses). In using this NOEL, it was assumed that developmental effects seen after multiple doses could be expressed following a single exposure. Furthermore, since teratogenic end-points are only relevant for women of child-bearing age, it was assumed that all other population sub-groups were as sensitive as this group. Both of these assumptions may underestimate the actual NOEL for single exposure.

For evaluating potential chronic dietary exposure, the NOEL (19.9 mg/kg/day) was obtained from a 1 year feeding study with dogs

(Bio/dynamics, 1986). This NOEL was based on minor liver effects seen at the next highest dose (230 mg/kg/day).

With experimentally determined NOEL's established, the potential dietary exposure to Londax® residues was evaluated for the general population and specific population sub-groups. As previously indicated, actual residue values for Londax® in agricultural commodities have not been determined. Tolerances were, therefore, used in estimating exposure.

The 95th percentile for acute exposure and the average chronic exposure, for the U.S. population, were estimated to be 0.052 and 0.004 ug/kg (body weight)/day respectively. The population sub-group with the highest estimated exposure was "Non-Hispanic-Other". Their estimated acute and chronic exposures were 0.178 and 0.016 ug/kg respectively.

Using the dietary exposure estimates and indicated NOEL's, margins of safety (MOS's) were calculated for various population sub-groups (MOS = NOEL/(dietary intake)). The estimated MOS's for the U.S. Population were 0.68×10^6 and 5.0×10^6 for acute and chronic exposure respectively. For acute exposure, the population sub-group exhibiting the lowest margin of safety (0.2×10^6) was the group classified as "Non-Hispanic-Other". For chronic exposure the population sub-group with the lowest MOS (0.9×10^6) was Non-Nursing Infants less than 1 year old. The group with the highest MOS for both acute and chronic exposure was females 13 + years old, who were pregnant but not nursing.

Even though this dietary assessment involved assumptions that may be regarded as conservative in nature (i.e., the use of tolerances to estimate human dietary exposure, and the use of teratology data to estimate acute exposure), the estimated margins of safety, for all population groups examined, were greater than 2×10^5 and are considered very health protective.

VII. CONCLUSIONS

Based on the current analysis, margins of safety for dietary exposure to Londax® are considered adequate to protect human health.

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Haskell Laboratory for Toxicology and Industrial Medicine, 1984e, du Pont de Nemours and Co. Inc. **Inhalation Median Lethal Concentration (LD_{50}) (in rats) of INF-5384-64 by EPA Guidelines.** Report Number 2267-84. DPR Document 50670-003 #38306.

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Haskell Laboratory for Toxicology and Industrial Medicine, 1984g, du Pont de Nemours and Co. Inc. **EPA Skin Irritation Study In Rabbits. Report Number 177-84.** DPR Document 50670-013 #41867.

Haskell Laboratory for Toxicology and Industrial Medicine, 1984h, du Pont de Nemours and Co. Inc. **Primary Skin Irritation and sensitization Test On Guinea Pigs.** Report Number 296-84. DPR Document 50670-003 #38308.

Haskell Laboratory for Toxicology and Industrial Medicine, 1984i, du Pont de Nemours and Co. Inc. **Median Lethal Dose (LD_{50}) of INF-5384-52 In rats - Intraperitoneal.** Report Number 252-84. DPR Document 50670-013 #41865.

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Haskell Laboratory for Toxicology and Industrial Medicine, 1986b, du Pont de Nemours and Co. Inc. **Acute Dermal Toxicity Study With INF-5384-85 In Rabbits.** Report Number 708-86. DPR Document 50670-015 #62103.

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Haskell Laboratory for Toxicology and Industrial Medicine, 1986d, du Pont de Nemours and Co. Inc. **Primary Dermal Irritation Study With INF-5384-85 In Rabbits.** Report Number 712-86. DPR Document 50670-015 #62104.

Haskell Laboratory for Toxicology and Industrial Medicine, 1986e, du Pont de Nemours and Co. Inc. **Median Lethal Dose (LD_{50}) of DPX-5384-10WP in Rats - EPA Proposed Guidelines.** Report Number 712-86. DPR Document 50670-015 #62104.

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APPENDIX A

LONDAX® HERBICIDE

LABELING

DUPONT

LONDAX®

HERBICIDE

REGISTRATION CODE 0289-000
PACKAGE SIZE 4 - 16.6 OUNCE BOXES

FOR USE ON RICE IN THE STATE OF CALIFORNIA

DRY FLOWABLE

ACTIVE INGREDIENTS	BY WEIGHT
Methyl 2-[[[(4,6-dimethoxypyrimidin-2-yl)amino]carbonyl]amino]sulfonyl]methyl]benzoate	60%
INERT INGREDIENTS	40%
	TOTAL 100%

EPA Reg. No. 352-506 U.S. Pat. 4,420,325

KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING ! CAUSES EYE IRRITATION.

Do not get in eyes, on skin or clothing. Wear goggles or face shield when handling. Avoid breathing spray mist. Harmful if swallowed. Wash contaminated clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT

If in eyes, immediately flush with plenty of water. Get medical attention.

If on skin, wash with plenty of soap and water. Get medical attention if irritation persists.

If swallowed, call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with fingers. Do not induce vomiting or give anything by mouth to an unconscious person.

For medical emergencies involving this product, call toll free:1-800-441-3637.

ENVIRONMENTAL HAZARDS

Do not apply directly to water or wetlands(swamps, bogs, marshes and potholes) except as specified on this label for use in rice. Do not contaminate water by cleaning of equipment or disposal of wastes.

IMPORTANT

Injury to or loss of desirable trees or vegetation may result from failure to observe the following:

Do not apply or drain or flush equipment on or near desirable trees or other plants, or on areas where their roots may extend, or in locations where the chemical may be washed or moved into contact with their roots.

Do not use on lawns, walks, driveways, tennis courts or similar areas. Prevent drift of spray to desirable plants.

Do not contaminate any body of water.

Keep from contact with fertilizers, insecticides, fungicides and seeds during storage.

Thoroughly clean all traces of "Londax" Herbicide from application equipment immediately after use and prior to spraying crops other than rice. Cleanup procedures are described in the "SPRAYER CLEANUP" section of this label. Failure to follow these procedures may result in injury to subsequently sprayed crops.

1

GENERAL INFORMATION

"Londax" Herbicide is a dry flowable formulation for selective preemergence and early postemergence weed control after establishment of the permanent flood. When applied according to the instructions on the label, it will control many broadleaf and sedge weeds. Best control will be achieved when "Londax" is applied to very young emerging and actively growing weeds (less than 3 leaves). Degree and duration of control may depend on: use rate, weed spectrum and infestation intensity, weed size at application time, growing conditions at and following time of treatment, soil pH, texture and organic matter, and water management.

Because most crops other than rice are highly sensitive to "Londax", all direct or indirect (such as spray drift) contact to crops or land scheduled to be planted to crops other than rice should be avoided as injury may result.

BIOLOGICAL ACTIVITY

"Londax" rapidly inhibits growth of susceptible weeds. Following preemergence to early postemergence applications (to weeds), leaves of susceptible plants will appear chlorotic in 3 to 5 days and necrosis of the growing point will subsequently occur. Susceptible plants are controlled in 7 to 21 days, depending on species, as evidenced by complete necrosis of the leaf tissue and growing point. In some cases, affected plants will be stunted and remain green, but are not competitive with the crop.

The herbicidal action of "Londax" may be influenced by temperature. Expression of herbicide symptoms is accelerated at warmer temperatures and may be delayed when air or water temperatures are below 65 degrees F. Under cool conditions, the appearance of chlorosis and eventual necrosis in susceptible plants may be delayed beyond 5 days. Occasional temporary chlorosis and/or growth retardation of rice may occur following "Londax" application. These symptoms are accentuated at high ambient temperatures and/or cold water temperatures. These symptoms are normally transient and disappear within 2 to 3 weeks after application.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in possession of the user at the time of pesticide application.

SPRAY TANK PREPARATION

"Londax" should be thoroughly mixed with water in a spray tank before adding any other material (i.e., antidrift agent). Agitation is required for uniform mixing and application. Apply "Londax" spray preparations within 24 hours of product mixing or product degradation may occur. Thoroughly reagitate before using.

"Londax" is compatible with many commercially available antidrift agents including, Nalcotrol[2], Unite[3], Poly Control[4], Air Drop[5], for example (polyvinyl alcohol or polyacrylamide based materials). Antidrift agents are recommended with applications of "Londax" in accordance with the labeling directions of the specific antidrift agent. Only antidrift agents approved by EPA can be used.

APPLICATION RECOMMENDATION

"Londax" must be applied after establishment of the permanent flood directly into standing water.

WATER SEEDED RICE

When applied as a water mixed spray, to water seeded rice, use a minimum of 5 gallons of water per acre. For best results, "Londax" should be applied preemergence to early postemergence to submerged weeds and post emergence to rice from the 1- to 3-leaf stage. Best control will be achieved when "Londax" is applied to very young emerging and actively growing weeds (less than 3 leaves) after establishment of the permanent flood. "Londax" can be applied to rice beyond the 3-leaf stage, but late applications should be targeted to the preemergence to early postemergence stage of weeds.

WATER MANAGEMENT FOLLOWING APPLICATION

Good water management at the time of "Londax" application and for at least 5 days following will ensure maximum product performance. Hold water static on the field for a minimum of 5 days after application. Holding water on the field for more than 5 days will enhance product performance. Failure to hold water for the 5-day minimum will decrease product performance. Rainfall sufficient to cause water flow off the field may reduce performance if it occurs within 5 days of application.

At the time of application and for the following 5 days, water on the field should be held static. Introduction of water may reduce herbicidal efficacy in areas adjacent to water inlet sites. Water level at the time of application and within 5 days of application should be high enough so that the soil is completely covered with water (preferably at least 3 inches with no exposed soil). Product performance will be reduced in areas where soil is not covered with water. Target weeds' foliage must remain covered with water at time of application and during the water holding period.

Note: Static water is defined as not allowing water to exit the field. Water may be introduced into the field to maintain flood level, but this may result in reduced control in areas around the water inlet(s).

WEEDS

"Londax" effectively controls the following weeds when used according to instructions on the label:

Blunt Spikerush: Eleocharis obtusa
California Arrowhead: Sagitaria montevidensis calycina
Duckssalad: Heteranthera limosa
Eisen waterhyssop: Bacopa eisenii
Purple ammania: Ammannia coccinea
Redstem: Ammannia auriculata
Roughseed bulrush: Scirpus mucronatus
Southern naiad: Najas guadalupensis
Smallflower umbrellaplant: Cyperus difformis
Water plantain (seedling) Alisma spp.
Waterwort: Elatine spp.

USE RATE: A maximum of 1 oz. active ingredient "Londax" Herbicide per acre per season is recommended.

The recommended rate in California is 1-2/3 oz. product per acre.

COMBINATION RECOMMENDATIONS

"Londax" may be used in conjunction with rice herbicides used for grass control. Sequential treatments of "Londax" with "Ordram"[6] or "Bolero"[7] will aid in control of barnyardgrass and watergrass, in addition to the above listed weeds. Applications of "Londax" should be made on the same day as "Ordram" and "Bolero" applications, if possible, or as soon as possible prior to or after application of these herbicides.

"Londax" can be applied following propanil applications. Do not apply "Londax" until a permanent flood has been established following propanil application.

"Londax" can be applied prior to propanil applications providing that all water management practices described by this label with respect to "Londax" use are followed.

Observe all applicable directions, restrictions (including water holding requirements) and precautions on the "Ordram", "Bolero" and propanil labels.

"Londax" has been successfully tank mixed with Red Top Methyl Parathion 5 Spray[8] in California. Tank mixes containing "Londax" and this brand of parathion should be used immediately after mixing. Consult your local Du Pont representative if tank mixes with other brands of parathion are planned.

SPRAYER CLEANUP

IMPORTANT - When "Londax" is applied as a spray, tank and spray equipment clean out is important and should be done immediately after spraying to avoid subsequent injury to crops other than rice. Use the following procedure for spray equipment clean out before using sprayer to treat rice:

1) Drain tank, then flush tank, boom and hoses with clean water for 10 minutes.

2) Repeat Step 1.

3) Fill the tank with clean water, then add Nutra-Soil[9] at a rate of 32 ounces of product per 100 gallons of water. Flush through the boom and hoses, then allow to sit for 15 minutes with agitation (and recirculation, if possible); drain equipment making sure to flush the boom and all hoses thoroughly.

4) Nozzles and screens should be removed and cleaned separately.

5) Thoroughly rinse sprayer, boom and hoses with clean water to remove Nutra-sol.

6) The rinsate may be disposed of on site or at an approved waste disposal facility.

Use this clean-out procedure if the sprayer will be used to treat crops other than rice:

1) Drain tank, then flush tank, boom and hoses with clean water for 10 minutes.

2) Fill the tank with clean water, then add 1/2 gallon of chlorine bleach (containing 5 1/4% sodium hypochlorite) per 100 gallons of water. Flush through boom and hoses, allow to sit for 15 minutes with agitation, then drain.

3) Repeat step 2.

4) Nozzles and screens should be removed and cleaned separately. To remove traces of chlorine bleach, rinse the tank thoroughly with clean water and flush through hoses and boom.

5) Dispose of rinsates on site or at an approved waste disposal facility.

CAUTION: Do not use chlorine bleach with ammonia. All traces of liquid fertilizer containing ammonia, ammonium nitrate or ammonium sulphate must be rinsed with water from the mixing and application equipment before adding chlorine bleach solution. Failure to do so will release a gas with a musty odor which can cause eye, nose, throat and lung irritation. Do not clean equipment in an enclosed area.

RESTRICTIONS

Do not apply more than 1 oz. active ingredient "Londax" per acre per season(1 2/3 oz. product).

Do not graze treated fields or feed treated forage within 80 days of last application.

Do not apply "Londax" within 80 days of harvest.

Do not apply "Londax" to rice under stress from abnormal weather or growing conditions, drought, disease, insect or prior herbicide injury, as crop injury may occur. Severe stress, drought, disease or insect damage following application may also result in crop injury.

Water drained directly from treated fields must not be used to irrigate other crops.

Do not mix "Londax" with any additives except as directed by this label.

Do not use "Londax" on wild rice (Zizania aquatica).

Do not rotate to crops other than rice for 120 days following application.

Londax - Registered trademark of E. I. Du Pont de Nemours & Co. (Inc.).
[2] Nalcotrol is a product of Nalco Chemical Company, Carson, California.
[3] Unite is a product of Hopkins Agricultural Chemical Company, Madison, Wisconsin.
[4] Poly Control is a product of JLB International Chemical Company, Inc., Vero Beach, Florida.
[5] Air Drop is a product of Knapp Manufacturing Co., Fresno, California.
[6] Registered trademark of ICI Americas, Inc., Wilmington, Delaware.
[7] Registered trademark of Chevron Chemical Company, San Francisco, California.
[8] Red Top Methyl Parathion 5 Spray is a product of Wilbur Ellis Company, Fresno, California.
[9] Nutra-Sol is a product of Thomas G. Kilfoil Company, Inc., San Bruno, California.

STORAGE AND DISPOSAL

STORAGE: Store product in original container only, away from other pesticides, fertilizer, food or feed. Not for use or storage in or around the home. Keep container closed.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal. Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Emptied paper (or cardboard) containers may be burned if allowed by state and local authorities. If burned, stay out of smoke.

NOTICE TO BUYER Purchase of this material does not confer any rights under patents of countries outside the United States.

3

NOTICE OF WARRANTY

Du Pont warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purposes stated on such label only when used in accordance with the directions under normal use conditions. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Du Pont. In no case shall Du Pont be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the buyer. DU PONT MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

D 051689

LABELING ACCEPTABLE

STATE OF CALIFORNIA
DEPARTMENT OF FOOD AND AGRICULTURE
PESTICIDE REGISTRATION

Date 5-25-89 Reviewer KBL

Reg. No. 352-506-AA

DUPONT

LONDAX® HERBICIDE
APPLIED DRY BY AIR
(WITHOUT A LIQUID CARRIER)
IN THE STATE OF CALIFORNIA

LONDAX® HERBICIDE

(EPA Reg. No. 352 - 506)
SUPPLEMENTAL LABELING
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF CALIFORNIA

APPLIED DRY BY AIR (WITHOUT A LIQUID CARRIER) IN THE STATE OF CALIFORNIA

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

GENERAL

This label allows for application of "Londax" Herbicide dry by air (without dilution in a liquid carrier) for weed control in water seeded rice, in the State of California. When applied according to the instructions on this label, "Londax" applied dry by air is effective for the control of many broadleaf and sedge weeds in water seeded rice. However, special equipment is required for this method of application.

HOW TO USE

APPLICATION INSTRUCTIONS

"Londax" Herbicide may only be applied dry by air in equipment approved by both Du Pont and the Federal Aviation Administration (FAA).

"Londax" Herbicide may only be applied dry by air by certified applicators using Du Pont certified equipment.

To apply "Londax" Herbicide dry by air, follow the loading and application instructions provided by the equipment manufacturer.

Before applying this product dry by air, calibrate equipment as described by the equipment manufacturer.

Do not mix "Londax" Herbicide to be applied dry by air with any liquid carrier (such as water or oil) and do not mix with any surfactant or crop oil.

Because most crops other than rice are highly sensitive to "Londax", all direct or indirect (such as spray drift) contact to crops (or land scheduled to be planted to crops) other than rice should be avoided, as injury may result.

Equipment designed for application of "Londax" Herbicide dry by air to rice must not be used to apply any product to any crop other than rice, as injury may result.

TIMING:

Apply "Londax" Herbicide dry by air to water seeded rice after the establishment of the permanent flood.

Target weeds must be covered with water at time of application. Water level should be high enough so that the soil is completely covered with water (preferably 3 inches deep with no exposed soil).

For best results, apply this product preemergence or early postemergence to submerged weeds and postemergence to rice in the 1 to 3 leaf stage.

WATER MANAGEMENT FOLLOWING APPLICATION:

Target weeds must remain covered with water for 5 days after application.

Water level should be high enough so that the soil is completely covered with water (preferably at least 3 inches deep with no exposed soil). Product performance will be reduced in areas where soil is not covered with water.

Hold water static on the field for a minimum of 5 days after application. Holding water static on the field for more than 5 days will enhance product performance; failure to hold water static for the 5 day minimum will decrease product performance. (Note: Static water is defined as not allowing water to enter or exit the field. Water may be introduced into the field to maintain flood level, but this may result in reduced control in areas around the water inlet(s)).

Rainfall sufficient to cause water flow off the field may reduce performance if it occurs within 5 days of application.

USE RATE/WEED CONTROLLED:

The recommended rate of "Londax" Herbicide applied dry by air in California is 1 2/3 oz product per acre (equivalent to 1 oz active ingredient per acre).

"Londax" Herbicide, applied dry by air according to the instructions on this label, will effectively control the weeds specified on the "Londax" label.

APPENDIX A (continued)

PRECAUTIONS:
Do not apply more than 1-2/3 oz. of "Londax" per acre per year.

Do not make more than one application of "Londax" per use season.

Do not apply "Londax" dry by air simultaneously with any other application.

Do not use a swath width greater than 60 feet when applying "Londax" dry by air

Apply "Londax" dry by air at a maximum height of no greater than 1/2 the wing span of the aircraft.

Do not apply "Londax" dry by air at wind speeds of greater than 10 mph.

Do not apply within 80 days of harvest.

Do not apply "Londax" dry by air to dry seeded rice.

Do not apply "Londax" within 50 feet of sensitive crops.

IMPORTANT

BEFORE USING "LONDAX" HERBICIDE, READ AND CAREFULLY OBSERVE THE CAUTIONARY STATEMENTS AND ALL OTHER INFORMATION APPEARING ON THE PRODUCT LABEL.

This bulletin contains new or supplemental information for use of "Londax" which does not appear on the product label.

This label must be in the possession of the user at the time of herbicide application.

091889 12/06/89
010991(replaces H-08163)

LABELING ACCEPTABLE
STATE OF CALIFORNIA
DEPARTMENT OF FOOD AND AGRICULTURE
PESTICIDE REGISTRATION
Date 2-22-91 Reviewer F. Bandak
Reg. No. 352-506-AA

APPENDIX B

Acute Dietary Exposure

APPENDIX B

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

U.S. POP - ALL SEASONS

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY: MG/KG BODY WT/DAY	MEAN DAILY EXPOSURE PER USER-DAY: MARGIN OF SAFETY
23.2%	0.000016	2221798

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	92976280	20.0	0.000024	1482816
80.0	0.000001	45758236	10.0	0.000036	969168
70.0	0.000002	15246756	5.0	0.000052	676837
60.0	0.000005	7453715	2.5	0.000075	469756
50.0	0.000008	4322483	1.0	0.000110	317520
40.0	0.000012	2984020	0.5	0.000160	218107
30.0	0.000017	2065455	0.0	0.000626	55945

WESTERN REGION

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY: MG/KG BODY WT/DAY	MEAN DAILY EXPOSURE PER USER-DAY: MARGIN OF SAFETY
26.0%	0.000016	2134963

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	115121384	20.0	0.000022	1573699
80.0	0.000001	57560692	10.0	0.000033	1067131
70.0	0.000001	32961338	5.0	0.000050	695568
60.0	0.000003	11798444	2.5	0.000069	505828
50.0	0.000007	5022534	1.0	0.000121	289590
40.0	0.000011	3215961	0.5	0.000304	114987
30.0	0.000015	2310608	0.0	0.000626	55945

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

HISPANICS

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
39.2%	0.000021	1670718

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000002	19065188	20.0	0.000033	1050737
80.0	0.000005	7773528	10.0	0.000049	719556
70.0	0.000008	4554832	5.0	0.000066	532840
60.0	0.000011	3081100	2.5	0.000080	435631
50.0	0.000016	2255532	1.0	0.000089	393965
40.0	0.000021	1699888	0.5	0.000113	309775
30.0	0.000025	1373371	0.0	0.000207	169006

NON-HISPANIC WHITES

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
20.4%	0.000012	2912507

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	114560632	20.0	0.000018	1904805
80.0	0.000001	52301036	10.0	0.000029	1215533
70.0	0.000001	23668692	5.0	0.000039	902966
60.0	0.000003	10387457	2.5	0.000050	700356
50.0	0.000006	5735285	1.0	0.000074	472378
40.0	0.000009	3690812	0.5	0.000099	354254
30.0	0.000013	2654886	0.0	0.000626	55945

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

NON-HISPANIC BLACKS

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
31.7%	0.000018	1918162

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000001	51774980	20.0	0.000031	1143331
80.0	0.000002	23226334	10.0	0.000042	836115
70.0	0.000004	8405084	5.0	0.000056	630125
60.0	0.000008	4655076	2.5	0.000074	475944
50.0	0.000013	2682962	1.0	0.000106	329991
40.0	0.000018	1994300	0.5	0.000128	273745
30.0	0.000023	1533588	0.0	0.000366	95509

NON-HISPANIC OTHER

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
44.3%	0.000051	682411

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000006	6008872	20.0	0.000087	404490
80.0	0.000013	2681908	10.0	0.000122	287321
70.0	0.000020	1714542	5.0	0.000178	196610
60.0	0.000025	1407509	2.5	0.000214	163604
50.0	0.000033	1057344	1.0	0.000262	133608
40.0	0.000045	785628	0.5	0.000303	115581
30.0	0.000059	589378	0.0	0.000410	85354

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

NURSING INFANTS (<1 YEAR)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY	
	MG/KG BODY WT/DAY	MARGIN OF SAFETY
58.3%	0.000024	1452027

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000001	27519546	20.0	0.000045	769386
80.0	0.000002	18658424	10.0	0.000062	561384
70.0	0.000003	10659709	5.0	0.000068	515923
60.0	0.000006	5793810	2.5	0.000071	495846
50.0	0.000019	1857637	1.0	0.000072	484532
40.0	0.000025	1420928	0.5	0.000073	480875
30.0	0.000031	1125717	0.0	0.000073	477273

NON-NURSING INFANTS (<1)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY	
	MG/KG BODY WT/DAY	MARGIN OF SAFETY
52.9%	0.000026	1337405

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000004	8873510	20.0	0.000046	757961
80.0	0.000006	5769919	10.0	0.000066	529323
70.0	0.000008	4505138	5.0	0.000081	430930
60.0	0.000010	3566653	2.5	0.000091	386586
50.0	0.000017	2081860	1.0	0.000145	241293
40.0	0.000025	1388016	0.5	0.000183	190932
30.0	0.000033	1049492	0.0	0.000207	169006

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

FEMALES (13+/PREG/NOT NSG)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
18.7%	0.000010	3633752

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	177613856	20.0	0.000017	2099219
80.0	0.000000	81555840	10.0	0.000029	1212382
70.0	0.000002	21947506	5.0	0.000033	1066317
60.0	0.000007	4983486	2.5	0.000035	1005734
50.0	0.000008	4242332	1.0	0.000038	910999
40.0	0.000009	3733494	0.5	0.000043	811894
30.0	0.000010	3333648	0.0	0.000048	732237

FEMALES (13+/NURSING)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
37.4%	0.000017	2047898

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000002	16710302	20.0	0.000017	2119760
80.0	0.000011	3319276	10.0	0.000035	1011283
70.0	0.000012	2944231	5.0	0.000045	786180
60.0	0.000013	2731732	2.5	0.000053	665717
50.0	0.000014	2547842	1.0	0.000075	467706
40.0	0.000015	2387149	0.5	0.000089	394561
30.0	0.000016	2245522	0.0	0.000103	341202

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

CHILDREN (1-6 YEARS)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY: MG/KG BODY WT/DAY	MEAN DAILY EXPOSURE PER USER-DAY: MARGIN OF SAFETY
29.7%	0.000022	1583109

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000001	60475232	20.0	0.000032	1084728
80.0	0.000001	30237616	10.0	0.000054	652751
70.0	0.000003	12191127	5.0	0.000082	428212
60.0	0.000007	4692249	2.5	0.000109	320022
50.0	0.000014	2500623	1.0	0.000179	195619
40.0	0.000017	2006955	0.5	0.000285	122899
30.0	0.000022	1621472	0.0	0.000410	85354

CHILDREN (7-12 YEARS)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY: MG/KG BODY WT/DAY	MEAN DAILY EXPOSURE PER USER-DAY: MARGIN OF SAFETY
31.0%	0.000018	1910611

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	77220432	20.0	0.000031	1138365
80.0	0.000001	38610216	10.0	0.000044	789763
70.0	0.000002	17077646	5.0	0.000071	492522
60.0	0.000005	7001625	2.5	0.000096	366362
50.0	0.000010	3559652	1.0	0.000111	316159
40.0	0.000017	2101529	0.5	0.000137	255167
30.0	0.000022	1585237	0.0	0.000233	150175

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

MALES (13-19 YEARS)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
26.1%	0.000014	2423193

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	89042152	20.0	0.000022	1604969
80.0	0.000001	43856756	10.0	0.000032	1105145
70.0	0.000001	23922384	5.0	0.000047	751016
60.0	0.000006	5512632	2.5	0.000066	534165
50.0	0.000011	3120474	1.0	0.000102	341749
40.0	0.000014	2470355	0.5	0.000148	237165
30.0	0.000018	1975045	0.0	0.000201	173887

FEMALES (13-19 YRS/NP/NN)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY MG/KG BODY WT/DAY	MARGIN OF SAFETY
26.3%	0.000010	3336894

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	163710448	20.0	0.000019	1891574
80.0	0.000000	81855224	10.0	0.000031	1119044
70.0	0.000001	54570144	5.0	0.000040	869230
60.0	0.000003	12977714	2.5	0.000045	774441
50.0	0.000005	7425932	1.0	0.000058	599064
40.0	0.000009	3964271	0.5	0.000065	536979
30.0	0.000013	2612869	0.0	0.000178	196516

EXPOSURE ANALYSIS FOR bensulfuron methyl
RESIDUE FILE NAME: BENSUL DATE OF ANALYSIS: 04-03-1991
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 35.000000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

MALES (20+ YEARS)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY: MG/KG BODY WT/DAY	MEAN DAILY EXPOSURE PER USER-DAY: MARGIN OF SAFETY
20.1%	0.000016	2202086

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	120811440	20.0	0.000022	1619266
80.0	0.000001	60405720	10.0	0.000032	1078611
70.0	0.000002	18674630	5.0	0.000047	739167
60.0	0.000004	8323660	2.5	0.000068	517056
50.0	0.000007	4856613	1.0	0.000129	270761
40.0	0.000010	3345369	0.5	0.000237	147484
30.0	0.000015	2346162	0.0	0.000626	55945

FEMALES (20+ YEARS/NP/NN)

ESTIMATED % OF POTENTIAL PERSON-DAYS THAT ARE USER-DAYS	MEAN DAILY EXPOSURE PER USER-DAY: MG/KG BODY WT/DAY	MEAN DAILY EXPOSURE PER USER-DAY: MARGIN OF SAFETY
20.6%	0.000013	2730610

PERCENT OF POPULATION EXCEEDING RfD (35.000000) = 0.0

ESTIMATED PERCENTILE OF POPULATION USER-DAYS EXCEEDING CALCULATED EXPOSURE IN MG/KG BODY WT/DAY AND CORRESPONDING MARGIN OF SAFETY (MOS)

PERCENTILE	EXPOSURE	MOS	PERCENTILE	EXPOSURE	MOS
90.0	0.000000	106288456	20.0	0.000021	1669900
80.0	0.000001	37335424	10.0	0.000033	1053961
70.0	0.000003	11949431	5.0	0.000045	784520
60.0	0.000004	7901265	2.5	0.000053	664581
50.0	0.000007	4930046	1.0	0.000094	371621
40.0	0.000010	3535151	0.5	0.000121	289429
30.0	0.000015	2410418	0.0	0.000170	205640

APPENDIX C

Chronic Dietary Exposure

APPENDIX C

EXPOSURE 1-87 ANALYSIS FOR bensulfuron methyl DATE: 04-03-199
RESIDUE FILE NAME: BENSUL ADJUSTMENT FACTOR #2 NOT USED
DATE RESIDUE FILE CREATED OR LAST UPDATED: 04-03-1991/14:01:15
DPR No Effect Level (NOEL) = 19.900000 MG/KG BODY WT/DAY
COMMENT: Residues set to tolerance levels

TOTAL EXPOSURE BY POPULATION SUBGROUP

POPULATION SUBGROUP	TOTAL EXPOSURE MG/KG BODY WT/DAY	TOTAL EXPOSURE MOS x 10^6	TOTAL EXPOSURE PERCENT OF DPR NOEL
U.S. POP - 48 STATES - ALL SEASONS	0.000004	5.0	0.00%
U.S. POPULATION - SPRING SEASON	0.000004	5.0	0.00%
U.S. POPULATION - SUMMER SEASON	0.000004	5.0	0.00%
U.S. POPULATION - AUTUMN SEASON	0.000003	6.6	0.00%
U.S. POPULATION - WINTER SEASON	0.000004	5.0	0.00%
NORTHEAST REGION	0.000003	6.6	0.00%
NORTH CENTRAL REGION	0.000003	6.6	0.00%
SOUTHERN REGION	0.000004	5.0	0.00%
WESTERN REGION	0.000004	5.0	0.00%
HISPANICS	0.000009	2.2	0.00%
NON-HISPANIC WHITES	0.000003	6.6	0.00%
NON-HISPANIC BLACKS	0.000007	2.8	0.00%
NON-HISPANIC OTHER THAN BLACK OR WHITE	0.000016	1.2	0.00%
NURSING INFANTS (<1 YEAR OLD)	0.000006	3.3	0.00%
NON-NURSING INFANTS (<1 YEAR OLD)	0.000023	0.87	0.00%
FEMALES (13+/PREGNANT/NOT NURSING)	0.000002	10	0.00%
FEMALES (13+/NURSING)	0.000006	3.3	0.00%
CHILDREN (1-6 YEARS)	0.000007	2.8	0.00%
CHILDREN (7-12 YEARS)	0.000006	3.3	0.00%
MALES (13-19 YEARS)	0.000004	5.0	0.00%
FEMALES (13-19 YRS/NOT PREG. OR NURSING)	0.000003	6.6	0.00%
MALES (20+ YEARS)	0.000003	6.6	0.00%
FEMALES (20+ YEARS/NOT PREG. OR NURSING)	0.000003	6.6	0.00%